

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-61. (Cancelled)

62. (Currently Amended) A composition comprising: a biologically active isolated Tat protein, a fragment thereof or mutant thereof, or a combination thereof, in a non-aggregated and non-oxidized form and in a form suitable for administration to a human, in combination with a suitable excipient and/or diluent, wherein said Tat protein, fragment or mutant, or combination thereof, 1) is internalized by activated endothelial cells or dendritic cells, which internalization is determined by incubating the activated endothelial cells or the dendritic cells with 10 ng/ml of said Tat protein, fragment or mutant, or combination thereof, which is labeled with rhodamine and detecting the rhodamine in the activated endothelial cells or the dendritic cells by fluorescence microscopy and 2) performs at least one action selected from the group consisting of the following actions: i) activates the proliferation, migration and invasion of Kaposi's sarcoma (KS) cells or cytokine-activated endothelial cells in culture when said Tat protein, fragment or mutant, or combination thereof, is present at a concentration of 10 ng/ml; ii) activates virus replication when added to infected cells as measured by a) the rescue of Tat-defective proviruses in HLM-1 cells after the addition of exogenous protein and/or b) the transactivation of HIV-1 gene expression in cells transfected with HIV-1 promoter-reporter plasmid; and iii) induces in mice the development of KS-like lesions in the presence of angiogenic factors or inflammatory cytokines.

63. (Previously Presented) The composition according to claim 62, wherein the biologically active isolated Tat protein, fragment or mutant, or combination thereof, is purified.

64. (Cancelled)

65. (Previously Presented) The composition according to claim 62, which comprises biologically active isolated wild type Tat protein.

66. (Currently Amended) The composition according to claim 62, 63 or 65, wherein the in a form suitable for administration is selected from the group consisting of mucosal, nasal, oral, vaginal, rectal, intramuscular, subcutaneous, intradermal, systemic, and local administration.

67. (Cancelled)

68. (Previously Presented) The composition according to claim 63, wherein said biologically active isolated Tat protein, fragment or mutant thereof, is purified by a method comprising performing heparin affinity chromatography.

69. (Previously Presented) The composition according to claim 68, wherein said performing step is followed by steps of (a) lyophilizing the biologically active isolated Tat protein, fragment or mutant, and (b) resuspending said lyophilized biologically active isolated Tat protein, fragment or mutant, in a degassed buffer.

70-75. (Cancelled).

76. (Currently Amended) Biologically active isolated Tat protein, a fragment thereof or mutant thereof, or combination thereof, which is in a non-aggregated and non-oxidized form and in a form suitable for administration to a human, and wherein said Tat protein, fragment or mutant, or combination thereof, 1) is internalized by activated endothelial cells or dendritic cells, which internalization is determined by incubating the activated endothelial cells or the dendritic cells with 10 ng/ml of said Tat protein, fragment or mutant, or combination thereof, which is labeled with rhomadine and detecting the rhodamine in the activated endothelial cells or the dendritic cells by fluorescence microscopy and 2) performs at least one action selected from the group consisting of the following actions: i) activates the proliferation, migration and invasion of Kaposi's sarcoma (KS) cells or cytokine-activated endothelial cells in culture when said Tat protein, fragment or mutant, or combination thereof, is present at a concentration of 10 ng/ml; ii) activates virus replication when added to infected cells as measured by a) the rescue of Tat-defective proviruses in HLM-1 cells after the addition of exogenous protein and/or b) the transactivation of HIV-1 gene expression in cells transfected with HIV-1 promoter-reporter plasmid; and iii) induces in mice the development of KS-like lesions in the presence of angiogenic factors or inflammatory cytokines.

77. (Previously Presented) The biologically active Tat protein, fragment or mutant, or combination thereof, according to claim 76, which is purified.
78. (Cancelled)
79. (Previously Presented) The biologically active isolated Tat protein, fragment or mutant, or combination thereof, according to claim 76, which is biologically active isolated wild type Tat protein.
- 80-88. (Cancelled)
89. (Previously Presented) The composition of claim 62, 63 or 65 which further comprises a biologically acceptable fluid.
90. (Currently Amended) A product which is produced by a process of lyophilizing ~~lyophilized form of~~ the composition of claim 62, 63 or 65.
91. (Previously Presented) A product which is produced by a process of lyophilizing the composition of claim 62, 63 or 65 and resuspending the lyophilized composition in a biologically acceptable fluid.
92. (Previously Presented) The composition of claim 65 wherein the amino acid sequence of said biologically active isolated wild type Tat protein consists of SEQ ID. No. 2.
93. (Previously Presented) The composition of claim 89 wherein the biologically acceptable fluid is serum, plasma, or one or more fractions thereof.
94. (Previously Presented) The composition of claim 91 wherein the biologically acceptable fluid is serum, plasma, or one or more fractions thereof.
95. (Previously Presented) The composition of claim 62, 63, 65, or 69 which further comprises an adjuvant.
96. (Previously Presented) The composition of claim 95 which further comprises a biologically acceptable fluid.
97. (Previously Presented) The composition of claim 95 wherein the adjuvant is RIBI, alum, or ISCOM, or a combination thereof.

98. (Previously Presented) The composition of claim 62, 63 or 65 in which said biologically active isolated Tat protein, fragment or mutant, or combination thereof, is bound to a delivery vehicle.
99. (Previously Presented) The composition of claim 98 in which said delivery vehicle is a nanoparticle.
100. (Previously Presented) The composition of claim 98 in which said delivery vehicle is an autologous erythrocyte.
101. (Previously Presented) The composition of claim 66 which is formulated for systemic delivery.
102. (Previously Presented) The composition of claim 66 which is formulated for intradermal delivery.
103. (Previously Presented) The composition of claim 66 which is formulated for subcutaneous delivery.
104. (Previously Presented) The composition of claim 103 which further comprises Alum.
105. (Previously Presented) The composition of claim 66 which is formulated for mucosal delivery.
106. (Currently Amended) The composition of claim 95, wherein the ~~which is in a form suitable for~~ administration is selected from the group consisting of mucosal, nasal, oral, vaginal, rectal, intramuscular, subcutaneous, intradermal, systemic, and local administration.
107. (Currently Amended) The composition of claim 106, wherein the administration ~~which is~~ by ~~formulated for~~ systemic delivery.
108. (Currently Amended) The composition of claim 106, wherein the administration ~~which is~~ by ~~formulated for~~ intradermal delivery.
109. (Currently Amended) The composition of claim 106, wherein the administration ~~which is~~ by ~~formulated for subcutaneous~~ subcutaneous delivery.
110. (Previously Presented) The composition of claim 109 which further comprises Alum.

111. (Currently Amended) The composition of claim 106, wherein the administration which is ~~by formulated for~~ mucosal delivery.
112. (Previously Presented) The composition of claims 62, 63, 65, or 69, in which said biologically active isolated Tat protein, fragment or mutant, or combination thereof, is conjugated to a T-helper peptide or T-helper universal epitope of Tetanus Toxoid.
113. (Previously Presented) The composition of claims 62, 63, 65, or 69, which further comprises an HIV antigen from an HIV protein other than a Tat protein.
114. (Previously Presented) The composition of claim 113, in which said HIV antigen is rev, nef or gag, or an immunogenic fragment thereof.
115. (Previously Presented) The composition of claims 62, 63, 65, or 69, which further comprises an immuno-modulant molecule.
116. (Previously Presented) The composition of claim 115, in which said immuno-modulant molecule is a cytokine.
117. (Previously Presented) The composition of claim 116, in which said cytokine is IL-12 or IL-15.
118. (Previously Presented) The composition of claims 62, 63, 65, or 69, in which said biologically active isolated Tat protein, mutant or fragment is fused to an HIV antigen from an HIV protein other than a Tat protein.
119. (Previously Presented) The composition of claim 118, in which said HIV antigen is rev, nef or gag, or an immunogenic fragment thereof.
120. (Previously Presented) The composition of claims 62, 63, 65, or 69, in which said biologically active isolated Tat protein, mutant or fragment is fused to an immuno-modulant protein.
121. (Previously Presented) The composition of claim 120, in which said immuno-modulant protein is a cytokine.
122. (Previously Presented) The composition of claim 121, in which said cytokine is IL-12 or IL-15.

123. (Previously Presented) The composition of claim 62, 63, 65, or 69, which further comprises an inhibitor of viral replication.
124. (Withdrawn) The composition of claim 62, 63, or 69, which comprises a biologically active isolated mutant Tat protein.
125. (Withdrawn) The composition of claim 124, wherein the amino acid sequence of said biologically active isolated mutant Tat protein consists of SEQ ID NO. 7, 8, 9, or 10.
126. (Withdrawn) The composition of claim 125, wherein the amino acid sequence of said biologically active isolated mutant Tat protein consists of SEQ ID NO. 7.
127. (Previously Presented) The composition of claim 62, 63, or 69, which comprises a biologically active isolated fragment of a Tat protein.
128. (Previously Presented) The composition of claim 127 wherein the amino acid sequence of said biologically active isolated fragment consists of SEQ ID NO. 11, 12, 13, 14, 15, 16, or 17.
129. (Previously Presented) The biologically active isolated Tat protein or mutant or fragment thereof of claim 79 wherein the amino acid sequence of said wild type Tat protein consists of SEQ ID NO. 2.
130. (Withdrawn) The biologically active isolated Tat protein or mutant or fragment thereof of claim 76, which is a biologically active isolated mutant Tat protein.
131. (Withdrawn) The biologically active isolated Tat protein or mutant or fragment thereof of claim 130, wherein the amino acid sequence consists of SEQ ID NO. 7, 8, 9, or 10.
132. (Withdrawn) The biologically active isolated Tat protein mutant or fragment thereof of claim 131, wherein the amino acid sequence of said biologically active isolated mutant Tat protein consists of SEQ ID NO. 7.
133. (Previously Presented) The biologically active isolated Tat protein or mutant or fragment thereof of claim 76, which is a biologically active isolated fragment of a Tat protein.

134. (Withdrawn) The biologically active isolated Tat protein or mutant or fragment thereof of claim 133, wherein the amino acid sequence of said biologically active isolated fragment consists of SEQ ID NO. 11, 12, 13, 14, 15, 16, or 17.

135. (Previously Presented) The biologically active isolated Tat protein or mutant or fragment thereof of claim 76, which is fused to an HIV antigen from an HIV protein other than a Tat protein.

136. (Previously Presented) The biologically active isolated Tat protein or mutant or fragment thereof of claim 135, in which said HIV antigen is rev, nef or gag, or an immunogenic fragment thereof.

137. (Previously Presented) The biologically active isolated Tat protein or mutant or fragment thereof of claim 76, which is fused to an immuno-modulant protein.

138. (Previously Presented) The biologically active isolated Tat protein or mutant or fragment thereof of claim 137, in which said immuno-modulant protein is a cytokine.

139. (Previously Presented) The biologically active isolated Tat protein or mutant or fragment thereof of claim 138, in which said cytokine is IL-12 or IL-15.

140. (New) The composition of claim 62, wherein the human is infected with HIV.

141. (New) The biologically active Tat protein, fragment or mutant, or combination thereof, according to claim 76, wherein the human is infected with HIV.